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U.S. NUCLEAR REGULATORY COMMISSION

10 CFR PART 110

RIN

[NRC-2012-0008]

Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final Branch Technical Position.

SUMMARY: In 2010, the U.S. Nuclear Regulatory Commission (NRC) staff published a final rule amending its regulations concerning export and import of nuclear equipment and material. Among other things, it added the phrase “of U.S. origin” to the first exclusion to the definition of “radioactive waste” to confirm that the return of U.S. origin radioactive sources is not classified as the import of radioactive waste. The NRC staff drafted the Branch Technical Position (BTP) on the Import of Non-U.S. Origin Sources to provide additional guidance on the application of this exclusion in the regulations.

In developing this BTP, the NRC staff has engaged with States, Low-Level Waste Compacts, industry, and the public by providing two opportunities for public comment via *Federal Register* Notice and a public meeting in 2012. The exclusion in 10 CFR Part 110 reflects the United States’ commitments to the policy of safe storage and disposal of disused sources in the international context, including under the Code of Practice on the International Transboundary Movement of Radioactive Waste (Code of Practice), Joint Convention on the Safety of Spent

Fuel Management and the Safety of Radioactive Waste Management (Joint Convention), and the International Atomic Energy Agency's (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct- along with the supplementary Guidance on Import and Export). The United States' commitments include not exporting radioactive waste to other countries for disposal and, in light of the United States' strong domestic regulatory program, allowing return of disused sources manufactured or distributed from the United States in order to prevent sources from being orphaned overseas where regulatory programs may not exist or function to an optimal level.

DATES: The BTP is effective on [INSERT DATE THAT IS 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal e-Rulemaking Portal: Go to <http://www.regulations.gov> and search for documents filed under Docket ID [NRC-2007-0009]. Address questions about NRC dockets to Ms. Carol Gallagher at 301-492-3668 or by e-mail Carol.Gallagher@nrc.gov.

NRC's Public Document Room (PDR): The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the

documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Jennifer C. Tobin, Office of International Programs, U.S. Nuclear Regulatory Commission, MS-O4E21, Washington, DC 20555-0001; telephone: (301) 415-2328; e-mail: jennifer.tobin@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. History

II. Branch Technical Position

III. Analysis of Public Comments on Proposed Branch Technical Position

I. History

The NRC published "Notice of Public Meeting and Request for Comment on the BTP on the Import of Non-U.S. Origin Radioactive Sources," 77 Fed. Reg. 2924 (January 20, 2012), and received five comment letters as a result of that publication. The NRC staff made no substantive changes to the draft BTP based on these comment letters. However, minor editorial changes were made to the draft BTP to provide greater clarity.

The NRC published "Request for Comment on the BTP on the Import of Non-U.S. Origin Radioactive Sources," 77 Fed. Reg. 64435 (October 22, 2012), and received eight comment letters as a result of that publication. Many of those comments were on the existing regulations (10 CFR 110) rather than the BTP. This final BTP does not amend the regulations in 10 CFR Part 110; rather, it clarifies what is meant by "U.S. origin" and explains how the NRC staff interprets this exclusion to the definition of "radioactive waste" as used in 10 CFR 110.2. The

NRC staff response to the eight comment letters can be found in this *Federal Register* Notice as well as at ML13177A163.

II. Branch Technical Position

A. Introduction

The NRC's regulations in 10 CFR Part 110 (Part 110), "Export and Import of Nuclear Equipment and Material," establish the general and specific export and import licensing requirements for special nuclear, source, and byproduct material including radioactive waste. "Radioactive waste" is defined in 10 CFR 110.2 as:

"...[a]ny material that contains or is contaminated with source, byproduct or special nuclear material that by its possession would require a specific radioactive material license in accordance with this Chapter [10 CFR Chapter I] and is imported or exported for the purposes of disposal in a land disposal facility as defined in 10 CFR Part 61, a disposal area as defined in Appendix A of 10 CFR Part 40, or an equivalent facility...."

There are six exclusions in 10 CFR 110.2 to the definition of "radioactive waste." The sealed source exclusion (exclusion one) is defined as radioactive material that is "[o]f U.S. origin and contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source."¹ Disused sources that satisfy an exclusion to the definition of "radioactive waste" may be imported (returned) under the general license in

¹ The NRC provided the following guidance on the scope of "U.S. origin" on NRC's Export and Import Web page at (<http://www.nrc.gov/about-nrc/ip/export-import.html>): "U.S. origin was added in the first exclusion to the definition of radioactive waste to clarify that the exclusion only applies to sources of U.S. origin. U.S. origin sources may include sources with U.S. origin material and sources or devices manufactured, assembled or distributed by a U.S. company from a licensed domestic facility. Disused sources that originated in a country other than the United States would require a specific license if being exported or imported for disposal."

10 CFR 110.27, which requires that the U.S. consignee be authorized to receive and possess the material under the relevant NRC or Agreement State regulations and that the importer satisfy the terms for the general license set forth in 10 CFR 110.50.

The NRC staff has developed this BTP to provide guidance to source manufacturers, distributors, or other entities on the NRC's application of the sealed source exclusion to imports into the United States of non-U.S. origin disused sources.²

B. Background

On July 28, 2010, the NRC published a final rule in the *Federal Register* (75 FR 44072) that amended several provisions in 10 CFR part 110 to improve NRC's regulatory framework for the export and import of nuclear equipment, material, and radioactive waste. The sealed source exclusion to the definition of "radioactive waste" was revised, in response to a comment, to confirm that the exclusion only applies to sources of "U.S. origin" being returned to an authorized domestic licensee. The addition of the term "U.S. origin" to the sealed source exclusion was consistent with the original intent of the exclusion, initially adopted in a 1995 rule.³

In September 1990, the IAEA General Conference adopted the Code of Practice on the International Transboundary Movement of Radioactive Waste (Code of Practice) which provides that "[t]he sending State should take the appropriate steps necessary to permit readmission into its territory of any radioactive waste previously transferred from its territory if such transfer is not or cannot be completed in conformity with this Code..., unless an alternate safe arrangement can be made." This Code of Practice served as a basis for the sealed source exclusion in the

² The terms "supplier" and "importer" are used interchangeably in this document with "manufacturers, distributors, or other entity."

³ Import and Export of Radioactive Waste, 60 FR 37556 (July 21, 1995).

1992 proposed rule (57 FR 17859) that described a United States policy of encouraging the return of disused sources to the country of origin for the purposes of helping to ensure that the sources will be handled responsibly at the end of their life cycle. The regulatory history of this rule, finalized in 1995 (60 FR 375567), was in principal and intent identical to the sealed source exclusion embraced by the proposed rule. In the Statements of Consideration, the NRC described industry practice as limited to return of disused sources to the original supplier or country of origin.

Shortly thereafter, the adoption of the Code of Practice resulted in the international development of the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (Joint Convention) that opened for signature in September 1997 and entered into force in 2001. In terms of this BTP, a key point in the legally-binding Joint Convention to which the United States is a party, is found in Article 28, "Disused Sealed Sources," which states:

"A Contracting Party shall allow for reentry into its territory of disused sealed sources if, in the framework of its national law, it has accepted that they be returned to a manufacturer qualified to receive and possess the disused sealed sources."

Nearly identical language was included in the non-legally binding Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct), along with the supplementary Guidance on Import and Export, that was internationally approved in 2003 and to which the United States made a political commitment in 2004. In accordance with the Code of Practice, the Joint Convention, and the Code of Conduct (including the supplemental Guidance on Import and Export), the NRC believed that encouraging return of disused sources to the country of origin would help prevent sources from becoming "orphaned" by facilitating responsible

handling of sources at the end of their life cycle. See *Import and Export of Radioactive Waste*, 57 FR 17859, 17861 (July 21, 1992) (proposed rule):

(“the return of used or depleted sealed sources, gauges, and similar items to the U.S. or to another original exporting country for reconditioning, recycling or disposal may * * * help ensure that such materials are handled responsibly and not left in dispersed and perhaps unregulated locations around the world”).

The NRC’s willingness to embrace this policy was in large part informed by U.S. industry comments that there is a:

“widely accepted practice, usually rooted in a sales or leasing contract or other agreement, of returning depleted sealed radioactive sources, used gauges, and other instruments containing radioactive materials * * * to the original supplier/manufacturer for recycle or disposal.” (57 FR 17864)

See *also*, e.g., *id.* at 17861 (“the sale of a source is often conditioned on later return of the source for disposal”). Accordingly, central to the sealed source exclusion was the NRC’s understanding, based on U.S. industry representations, that new and disused sources are routinely exchanged on a “one-for-one” basis—*i.e.*, a new source is exchanged for a disused source⁴—with the result that the number of disused sources imported is not greater than the number of new sources exported.

After the addition of “U.S. origin” to the sealed source exclusion in the 2010 rule, it came to the NRC staff’s attention that, while it remains a widespread industry practice to exchange new and disused sources on a “one-for-one” basis, the current global supply market does not always

⁴ The sealed sources are changed out when the decay of the source limits the usefulness of the material. At this point, a supplier typically will send a new source and the user will return the used source in the same shielded container. This practice is typically formalized in the contract between the user and the supplier. Sometimes the sources are still useful and can be recycled for re-use in a different application. In that case, the sixth exclusion to the definition of “radioactive waste” applies and the source can be imported under a general license even if it is non-U.S. origin. Guidance on this exclusion can be found on NRC’s Export and Import Web page at <http://www.nrc.gov/about-nrc/ip/export-import.html> and is in harmony with this position paper.

allow a supplier to definitively ascertain the origin of a particular disused source that is exchanged for a new one before import and receipt of the disused source. With established customers, the disused sources will generally be of U.S. origin; however, for new customers, some of the sources initially being returned may not be of U.S. origin. The result is still a “one-for-one” exchange, resulting in the number imported not being greater than new sources exported.

Once a source is imported and received, the manufacturer, distributor, or other entity technically has the ability to determine the source’s origin. However, the only way for the supplier to accomplish this is by exposing its personnel to additional radiation doses. Specifically, the supplier must use a glove-box to take the source out of its casing to read the serial numbers and correlate those numbers to different manufacturer’s coding patterns.

C. Regulatory Position

The NRC staff has construed the “U.S. origin” provision in the context of the industry’s recent clarification of international source exchange practices. The NRC staff recognizes that in some circumstances it may not be feasible for the importer to determine the country of origin for disused sources it seeks to exchange prior to import. If, after a good faith effort and without exposing personnel to additional doses, the U.S. manufacturer, distributor, or other entity cannot determine whether an imported disused source that has been exchanged for a new source is of U.S. origin, the source in question shall be deemed to be of U.S. origin for the purposes of the sealed source exclusion to the definition of “radioactive waste” in 10 CFR 110.2.⁵ This application of the sealed source exclusion is limited to disused sources imported into the United

⁵ The definition of “radioactive waste” in this BTP paper pertains solely to export and import. It does not affect or alter the domestic regulations of “waste” as defined in 10 CFR 20.1003.

States that have been exchanged for a new source in a foreign country on a “one-for-one” basis. Accordingly, it is the NRC’s expectation that the number of disused sources imported by the manufacturer or distributor into the United States must not be greater than the number of new or refurbished sources exported by that manufacturer or distributor.

The NRC staff believes that this application of the sealed source exclusion reasonably balances the interests of public health and safety and international policy interests in responsible handling of sources at the end of their useful life. The approach preserves the fundamental policy rationale underlying the original exclusion—to prevent sources from being dispersed in unregulated locations around the world by facilitating a “one-for- one” exchange of U.S.-supplied new and disused sources—while achieving occupational doses to workers that are as low as reasonably achievable, as specified in 10 CFR 20.1101(b).

The NRC staff expects U.S. manufacturers, distributors, and suppliers to make a good faith effort to determine source origin before an import occurs. A good faith effort by the importer includes, but is not limited to, communication of U.S. import requirements with its foreign customers, examination of a photograph of the source the customer seeks to exchange, and obtaining other relevant information related to the disused sources’ origin. It is recommended that U.S. importers retain copies of their communications with their foreign customers regarding U.S. import requirements. At all times, the U.S. importer must comply with the specific license requirement for disused sources known to be of non-U.S. origin prior to import into the United States. The specific license requirements include meeting the provisions/conditions of the material possession license which may limit the quantity/activity held in storage on site. Licensees should consider the potential ramifications and costs of extended storage due to lack of disposal options. Licensees should recognize that the low-level radioactive waste compacts have legal jurisdiction for the availability and access to disposal options.

Consistent with 10 CFR 110.53, the NRC staff may inspect the licensee's records, premises, and activities pertaining to its exports and imports to ensure compliance with the sealed source exclusion to the definition of "radioactive waste."

This position was distributed to all Agreement States and material licensees as a proposed document for comment and is publicly available for use by all potentially affected parties. Additionally, the NRC staff has coordinated this position with the Department of Energy/National Nuclear Security Administration's (DOE/NNSA) Global Threat Reduction Initiative (GTRI) and confirmed that NRC does not have jurisdiction over the GTRI program.

D. Implementation

This technical position reflects the current NRC staff position on acceptable use of the general license for import of disused radioactive sources. Therefore, except in those cases in which the source manufacturer or distributor proposes an acceptable alternative method for complying with the definition of "radioactive waste" in Section 110.2, the guidance described herein will be used in the evaluation of the use of the general import license for disused sources.

III. Analysis of Public Comments on Proposed Branch Technical Position

The NRC received responses from eight organizations including States, licensees, and others on the proposed BTP on the Import of Non-U.S. Origin Radioactive Sources, 77 Fed. Reg. 64435 (October 22, 2012) that was published for a 60-day public comment period. The commenters were: the Northwest Interstate Compact on Low-Level Radioactive Waste Management (Northwest Compact), the State of Utah's Department of Environmental Quality (UDEQ), the State of Virginia's Department of Health -Division of Radiological Health (State of Virginia), the Organization of Agreement States (OAS), the Nuclear Energy Institute (NEI), the

International Source Suppliers and Producers Association (ISSPA), QSA Global Inc. (QSA), the Low-Level Radioactive Waste Forum Inc.- Disused Sources Working Group (LLW Forum), and International Isotopes Inc. (International Isotopes).

Most of the comments did not disagree with the underlying rationale for the regulation in Part 110 and justification for the BTP's interpretation (i.e., to construe non-U.S. origin disused sources as U.S. origin under certain circumstances for purpose of exclusion one to the definition of radioactive waste in 10 CFR 110.2.) Instead, many of the comments appear to request that NRC revise or clarify the existing exclusions to the definition of radioactive waste in Part 110.

Although only minimal changes are being made to the proposed BTP (mainly to provide more historical background and context and to explicitly point out costs and access to limited disposal options), the NRC staff found the comments useful in identifying concerns and is formally responding to those comments in conjunction with publication of the final BTP in the *Federal Register*.

Comment Response

Comment: Four commenters (NEI, OAS, ISSPA, and the State of Virginia) agreed with the guidance provided in the proposed BTP and urged NRC staff to publish the final document in the *Federal Register* in the near future.

Response: The comment resolution document will be published in the *Federal Register* in conjunction with the final BTP.

Comment: International Isotopes and NEI requested that clarification regarding disused sources containing byproduct material as defined under section 11e(3) or section 11e(4) of the

Atomic Energy Act be included in the BTP. The commenters asked for “additional language to be added to the BTP to address the import of non-U.S. origin sources containing accelerator produced radioisotopes or Radium-226 which can be disposed of in non-Part 61 or equivalent facilities” as it was unclear to them if “equivalent facility” could include Resource Conservation and Recovery Act (RCRA) facilities.

To address this concern, International Isotopes suggested that a footnote be added to the BTP such as the following:

“Non-U.S. origin radioactive sources containing byproduct material, as defined in paragraphs (3) and (4) of the definition of “byproduct material” set forth in 20.1003, does not require a specific import license if it [the material] is intended for disposal at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.”

Response: Any disused source imported for disposal in a RCRA facility would not be treated as “radioactive waste” under NRC’s definition of radioactive waste found in 10 CFR Part 110.2 since it is not being disposed of in a Part 61, Part 40 (Appendix A) or equivalent facility.

Conversely, any disused source imported for disposal in a Part 61 or Part 40 (Appendix A), or equivalent facility, even if it contains section 11e(3) or section 11e(4) material, would qualify as radioactive waste under the Part 110 definition of “radioactive waste” since disposal would “...require a specific radioactive material license in accordance with this Chapter and is imported or exported for the purposes of disposal in a land disposal facility...” pursuant to NRC’s regulations. The term “equivalent facility” used here refers to Part 61 equivalent facilities in foreign countries for export purposes and does not relate to import of disused sources. This clarification is not directly related to the discussion of U.S. origin in the BTP and therefore has

been included as a frequently asked question (FAQ) on NRC's Web site at

<http://www.nrc.gov/about-nrc/ip/faq.html>.

Comment: QSA requested that the final BTP include clarification of Footnote 1 in the BTP⁶.

Specifically, QSA commented that:

"We understood that the draft BTP was going to further clarify, that if a non-U.S. origin source is contained in a U.S. device, and that U.S. device needs to be returned to the U.S. for use, then that can be considered a legitimate import regardless of the source origin. We suggest the BTP add further clarification on this point for sources returned in a device under footnote 1. This change will continue to support international commerce, and will not impose unfair competitive restrictions on U.S. manufacturers since many other countries do not have this restriction."

QSA explained that disused sources (both U.S. and foreign origin) are loaded into U.S. shipping containers, presumably when customers order replacement sources and if they have limited or no storage capacity for spent sources. QSA's interpretation of "U.S. origin" devices include U.S. shipping containers. Specifically, QSA uses the terms "device" and "shipping container" interchangeably in the 10 CFR 110.2 definition of "radioactive material."

The NRC staff believes that the guidance for "U.S. origin" in Footnote 1 is clearly addressing medical, industrial, or other types of sources that are included in devices. For those radiographic exposure devices, as defined in 10 CFR 34.3, which meet the performance

⁶ The NRC provided the following guidance on the scope of "U.S. origin" on NRC's Export and Import Web page at (<http://www.nrc.gov/about-nrc/ip/export-import.html>): "U.S. origin was added in the first exclusion to the definition of radioactive waste to clarify that the exclusion only applies to sources of U.S. origin. U.S. origin sources may include sources with U.S. origin material and sources or devices manufactured, assembled or distributed by a U.S. company from a licensed domestic facility. Disused sources that originated in a country other than the United States would require a specific license if being exported or imported for disposal."

requirement of 10 CFR 34.20(b)(2) and qualify as Type B transport containers in accordance with the applicable requirements of 10 CFR part 71, the radiographic exposure device houses the source and is integral to the use of the material for its intended purpose. The sealed source exclusion is applicable as is the “one-for-one” discussion. These are not the same as shipping containers that are used solely for transferring new or used sources. NRC does not consider a Type B shipping container that is not integral to the use of the material for its intended purpose to be a device, as the term is commonly used and understood in NRC’s domestic regulatory program. A device typically only contains one source whereas a shipping container can include a number of sources with different origins. All of the sources in the shipping container need to be taken into account in the one-to-one exchange and determining origin.

Comment: The LLW Forum requested that further interactions with the NRC take place regarding the first and sixth exclusions of the definition of “radioactive waste” in 10 CFR 110.2. The first exclusion addresses U.S. origin. The sixth exclusion concerns legitimate recycling of radioactive sources.

Response: As stated in the final rule, the NRC added a sixth exclusion to the definition of “radioactive waste” to clarify that the definition does not include material imported solely for the purposes of recycling and not for waste management or disposal where there is a market for the recycled material and evidence of a contract or business agreement can be produced upon request by the NRC.

In addition to the LLW Forum’s comment, the NRC also received several questions from industry regarding the applicability of the sixth exclusion to long-lived isotopes sealed in radioactive sources. Specifically, the NRC has been asked for clarification on the applicability of exclusion six in cases where sources were imported for recovery and reuse of the radioactive

material but, upon import, due to the condition of the source or device, it was determined that the material could not be recovered or reused as intended. The NRC staff recognizes that in some circumstances sources imported with the intent to recycle may be discovered to be not recyclable. The NRC staff construes the sixth exclusion in 10 CFR 110.2 to authorize import for recycle and/or reuse under the general license to apply in a situation where, based on the best available information and after a good faith effort to determine recyclability of the source(s) prior to the import taking place, a U.S. company imports a source with the intent of recovering the radioactive material for reuse in another application but upon import discovers that a source is not recyclable. A good faith effort by the importer includes, but is not limited to, communication of U.S. import requirements with its foreign customers, examination of a photograph of the source(s) the customer seeks to exchange, and other relevant information related to the source's recyclability such as current activity level.

At all times, the U.S. importer must comply with the specific license requirement for "radioactive waste" as defined in 10 CFR 110.2. Any person who imports materials under a general license for recycling using exclusion six, but with the intent of disposing of that material in the United States would be subject to NRC enforcement action. In addition, there may be instances in which some small value may be obtained from the materials that are imported, but the primary intention is for disposal. In such cases, to avoid possible enforcement action the NRC staff should be consulted before any such imports are made. It is recommended that U.S. importers retain copies of their communications with their foreign customers regarding U.S. import requirements and records of efforts taken to determine recyclability of the source(s) prior to import. This guidance is also posted as an FAQ on the import/export Web site at

<http://www.nrc.gov/about-nrc/ip/faq.html>.

Comment: The Northwest Compact pointed out that NRC's definition of radioactive waste to exclude U.S. origin disused sources is not consistent with the Compact's definition of radioactive waste in its "Resolution Clarifying the Third Amended Resolution and Order," which the Compact claims requires treating U.S.-manufactured disused sources that are used outside the U.S. as foreign radioactive waste. According to the Northwest Compact:

"A depleted sealed source means that the useful life of the returned radioactive sealed sources is exhausted or used up which means the Compacts would view such sources as radioactive waste. Following purchase from a U.S. manufacturer, the source spent its entire useful life employed for its specific purpose in the foreign country. So although the BTP would allow such sources to be returned to the manufacturer as material, in reality the radioactive sealed source actually became waste following its use within a foreign country, prior to its return to the U.S. manufacturer."

Furthermore, The Northwest Compact stated that:

"It is difficult to envision the return of a "depleted" radioactive sealed source as anything other than the return of waste that was generated within a foreign country. Without such a policy, there is little incentive for out-of-region states or foreign countries to develop the capacity to properly handle radioactive sealed sources following their useful life."

The Northwest Compact recommended that the NRC add a statement such as the following to the BTP:

"Returned sources may have limited disposal access as the interstate compacts in which three of the four operating Part 61 commercial disposal facilities in the U.S. are located may view the returned radioactive sealed sources as foreign low-level waste and would not provide access for disposal."

Response: The NRC disagrees that a U.S.-manufactured source that was used outside the U.S. should be treated as foreign-generated radioactive waste for purposes of import under Part 110. As stated in the BTP, facilitating return of U.S.-manufactured disused sources through the use of a general license, among other things, furthers international policy objectives regarding disused sources committed to by the United States, including the United States' implementation of the Code of Conduct. Specifically, paragraph 27 of the Code of Conduct states:

“Every State should allow for re-entry into its territory of disused radioactive sources if, in the framework of its national law, it has accepted that they be returned to a manufacturer authorized to manage the disused sources.”

The return of disused sources to the country of origin is a well-established industry practice not only in the United States but in many other countries. Global implementation of the Code of Practice, Joint Convention, and Code of Conduct (including the supplementary Guidance on Import and Export) provides responsible end-of-life management for all international parties (see Background section of BTP for additional details). The practice of allowing return to the U.S. under general license of U.S.-manufactured disused sources has been in use in the United States at least since the mid-1990's.

The NRC staff recognizes that differences in interpretation of the meaning of “foreign” radioactive waste may limit disposal options for licensees. The Northwest Compact's current “Resolution Clarifying the Third Amended Resolution and Order” would appear not to allow sources used in foreign jurisdictions (to the end of useful life) to be disposed of at a Compact facility even if a source originated in a Northwest Compact member state and is considered to be “U.S. origin” and excluded from the definition of radioactive waste by the NRC for purposes of import. The Northwest Compact thus purports to have the authority to prevent return to the U.S. of disused sources originating in the U.S. but used in a foreign country.

The NRC staff believes that the Northwest Compact's interpretation of country of origin and what is "foreign" waste is inconsistent with the commonly understood and accepted interpretation of country of origin for disused sources (i.e., the country where the disused sources were manufactured rather than used) under the international agreements to which the U.S. is a signatory, including the Code of Practice, the Joint Convention, and the Code of Conduct, all of which expect that signatory countries be responsible for the disposition of disused sources originating within their own country.

To the extent that the Northwest Compact is suggesting that its Compact authority may be exercised in a manner that is contrary to federal law, including NRC regulations, and underlying U.S. policy objectives to promote responsible handling of disused sources on an international scale, the NRC staff disagrees. Section 4(b)(4) of the Low Level Radioactive Waste Policy Act of 1985, as amended, provides that, "[e]xcept as expressly provided in this Act, nothing contained in this Act or any compact may be construed to limit the applicability of any Federal law or to diminish or otherwise impair the jurisdiction of any Federal agency. . . ." The NRC staff questions whether application of the Northwest Compact's "Resolution" in a manner that would interfere with the federal scheme for responsible disposition of U.S. origin disused sources used overseas, including disused sources originating within a Northwest Compact member state, would be a permissible exercise of Compact authority consented to by Congress under the Northwest Interstate Compact on Low-Level Radioactive Waste Management. The NRC staff recognizes, however, that legal and policy issues regarding the interface between federal authority and state compact authority have yet to be tested in this particular context and, in any event, are beyond the scope of the BTP. We reiterate that the BTP itself is consistent with the NRC rule regarding import and export of radioactive waste that has been in place since 1995, and, through its limitation to one-for-one exchanges, has a neutral effect on disposal capacity constraints within the U.S. The NRC staff also notes that the other nine Low-Level Waste

Compacts and ten unaffiliated States have not expressed specific views on the waste management practices that apply to disused radioactive sources.

By addressing this aspect of the Northwest Compact's comment in this comment resolution document (published at the same time as the BTP), the NRC is reiterating to licensees the potential limits both to disposal options for disused sources and long-term storage capacity at the licensees' respective sites.

Comment: Three commenters (Northwest Compact, LLW Forum and UDEQ) would like additional language added to the BTP to acknowledge the lack of current disposal options for non-U.S. origin disused radioactive sources. UDEQ commented that "[t]he importation of sources/devices not directly attributable to U.S.-origin certainly raises a concern regarding disposal site access in Utah." UDEQ suggested adding clarification to the BTP to state that where disposal of such sources is not an option, a licensee

"...would still be required to store these sources safely, to meet the financial assurance provisions as applicable in the regulations, and would have to dispose of the sources in an authorized facility at some time. The DEQ staff expects that licensees would consider the additional costs for potential storage and out-of-compact disposal in deciding whether to import sources..."

UDEQ also suggested adding more explanatory text regarding potential storage and disposal considerations and requirements directly into the BTP as a clarifying footnote. The Northwest Compact and LLW Forum raised similar concerns about potential impacts on capacity for domestic long-term storage and ultimate disposal by NRC and Agreement State licensees. Specifically, the LLW Forum observed that

"...although NRC may allow certain radioactive sources to be imported into the country under the proposed BTP, the agency should be aware that there may not

be a disposal option for the sources depending upon the policies of the particular Compact and/or sited state to which the sources are being returned.”

Response: A specific license for the import of radioactive waste must “...name an appropriate facility that has agreed to accept and is authorized to possess the waste for *management* or disposal...” (10 CFR 110.43(d) (emphasis added)) where “management” includes authorization for long-term storage under a company’s NRC or Agreement State issued possession license. A general license (10 CFR 110.27) is contingent on “the U.S. consignee [being] authorized to receive and possess the material under a general or specific NRC or Agreement State license...” Among other things, the domestic authorization sets possession limits and provisions for long-term storage. The NRC staff is aware that there may not be disposal options for some sources due to current Compact policies on admittance of out-of-Compact waste.

Agreement State and NRC possession license holders historically have not differentiated use or storage of radioactive sources based on origin. In terms of their possession limits and storage capacity, licensees handle the sources identically regardless of origin in order to protect public health and safety. With the “one-for-one” exchange required under the BTP, there should be no increase in the volume of disused sources for management or disposal as a result of the BTP. The application of this BTP is limited to those radioactive sources that have been exchanged on a “one-for-one” basis and after a good faith effort has been made by the importer to determine the origin. Accordingly, it is the NRC’s expectation that the number of disused sources imported by the manufacturer or distributor into the United States must not be greater than the number of new or refurbished sources exported by that manufacturer or distributor.

Comment: The Northwest Compact and the UDEQ suggested that the final BTP include language explicitly:

“...informing U.S. licensees to consider the ramifications and costs of the potential need for extended storage in the absence of a recycling or subsequent disposal option for imported sources and devices as well as the legal jurisdictions of low-level radioactive waste compacts in terms of the availability of or access to disposal activities.”

Response: The NRC is aware that the costs of long term storage may be an issue for some licensees. For this reason, NRC has added language to the final BTP to reflect the Northwest Compact and State of Utah concerns regarding the availability and access to the limited disposal options currently available.

Comment: The LLW Forum expressed that “the NRC should show greater deference to the LLW Compacts and host states through earlier and more active involvement in the import of potentially non-U.S. origin radioactive sources for disposal.” They suggest that:

“...when the NRC is in the process of developing policy positions on the disposal of disused sources, the NRC should evaluate whether the position is consistent with the policies of interstate compacts that host Part 61 commercial low-level radioactive waste disposal facilities and should also include consultation and communication with affected compacts and sited states.”

Response: The NRC staff works within the confines of the Atomic Energy Act of 1954, as amended, and recognizes the authorities granted to the States and Compacts in the Low Level Waste Policy Act of 1985. The LLW Compacts are provided multiple opportunities to comment on publications for rulemaking in Part 110, Part 110 specific license applications for import of radioactive waste, and guidance documents such as the BTP (see pre-emption response above).

Comment: International Isotopes suggested that the final BTP should “recognize the practice of a “one-for-one” source exchange and acknowledge that there are complexities associated the radioactive source supply chain.” More specifically, International Isotopes points out that the timing of exports and imports over the course of a timeframe might not align specifically with the “one-for-one” principle on which the BTP is based.

Response: The NRC staff recognizes that importing/exporting trends and an importer’s intent are licensee and isotope-specific and will be considered on a case-by-case basis by NRC staff.

Dated at Rockville, Maryland, this 22nd day of August, 2013.

For the Nuclear Regulatory Commission,

/RA/

Charlotte Abrams, Acting Director
Office of International Program

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